

CLAIMS

1. A biodegradable implant for treating sinusitis comprising a sustained release therapeutic agent dispersed within a biodegradable matrix, wherein the biodegradable implant has at least one characteristic that substantially prevents clearance of the implant from a sinus during a treatment period after delivery of the implant into the sinus.
2. The biodegradable implant of claim 1 wherein the at least one characteristic is size of the implant.
3. The biodegradable implant of claim 1 wherein the at least one characteristic is shape of the implant.
4. The biodegradable implant of claim 1 wherein the at least one characteristic is density of the implant.
5. The biodegradable implant of claim 1 wherein the at least one characteristic is viscosity of the implant.
6. The biodegradable implant of claim 1 wherein the at least one characteristic is mucoadhesiveness of the implant.
7. The biodegradable implant of claim 1 wherein the sustained release therapeutic agent is selected from the group consisting of anti-infective agents, anti-inflammatory agents, and combinations thereof.
8. The biodegradable implant of claim 1 wherein the sustained released therapeutic agent comprises an anti-infective agent.

9. The biodegradable implant of claim 8 wherein the anti-infective agent is selected from the group consisting of antibacterial agents, antifungal agents, antiviral agents, and antiseptics.

10. The biodegradable implant of claim 8 wherein the anti-infective agent comprises an antibacterial agent.

11. The biodegradable implant of claim 10 wherein the antibacterial agent is selected from the group consisting of aminoglycosides, amphenicols, ansamycins, β -lactams, lincosamides, macrolides, nitrofurans, quinolones, sulfonamides, sulfones, tetracyclines, and any of their derivatives.

12. The biodegradable implant of claim 10 wherein the antibacterial agent comprises a β -lactam.

13. The biodegradable implant of claim 12 wherein the β -lactam comprises a penicillin.

14. The biodegradable implant of claim 13 wherein the penicillin comprises amoxicillin.

15. The biodegradable implant of claim 1 wherein the sustained release therapeutic agent is an anti-inflammatory agent.

16. The biodegradable implant of claim 15 wherein the anti-inflammatory agent is a nonsteroidal anti-inflammatory agent or a steroidal anti-inflammatory agent.

17. The biodegradable implant of claim 1 wherein the sustained release therapeutic agent comprises a steroidal anti-inflammatory agent.

18. The biodegradable implant of claim 17 wherein the steroidal anti-inflammatory agent is selected from the group consisting of 21-acetoxypregnenolone, alclometasone, algestone, amcinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucoronide, flumethasone, flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol propionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 25-diethylamino-acetate, prednisolone sodium phosphate, prednisone, prednival, prednylidene, rimexolone, tixocortol, triamcinolone, triamcinolone acetonide, triamcinolone benetonide, triamcinolone hexacetonide, and any of their derivatives.

19. The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises budesonide.

20. The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises mometasone furoate.

21. The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises beclomethasone.

22. The biodegradable implant of claim 1 wherein the biodegradable matrix is a biodegradable polymer matrix.

23. The biodegradable implant of claim 1 wherein the biodegradable matrix comprises a mucoadhesive polymer.

24. The biodegradable implant of claim 23 wherein the mucoadhesive polymer is selected from the group consisting of homopolymers of acrylic acid monomers and their pharmaceutically acceptable salts; copolymers of acrylic acid and methacrylic acid, styrene, or vinyl ethers; polyhydroxyethyl acrylate; polyhydroxyethyl methacrylate; polyvinyl alcohol; polyvinyl pyrrolidone; methyl cellulose; ethyl cellulose; hydroxyethyl cellulose; hydroxypropyl cellulose; hydroxypropylmethyl cellulose; carboxymethyl cellulose; alginic acid; sodium alginate; tragacanth gum; collagen; gelatin; and any combination thereof.

25. The biodegradable implant of claim 1 wherein the biodegradable matrix comprises poly(lactic-co-glycolic)acid (PLGA) copolymer.

26. The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises amoxicillin.

27. The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises budesonide.

28. The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises mometasone furoate.

29. The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises beclomethasone.

30. The biodegradable implant of claim 1 wherein the biodegradable matrix comprises a poly(ortho ester).

31. The biodegradable implant of claim 1 wherein the treatment period is about one week to about three months.

32. The biodegradable implant of claim 1 wherein the treatment period is about two weeks to about 4 weeks.

33. The biodegradable implant of claim 1 wherein the implant is of a form selected from the group consisting of rods, pellets, beads, strips, and microparticles.

34. The biodegradable implant of claim 1 wherein the implant is a microparticle.

35. The biodegradable implant of claim 34 in a pharmaceutically acceptable carrier.

36. The biodegradable implant of claim 35 wherein the pharmaceutically acceptable carrier is a semi-solid gel.

37. The biodegradable implant of claim 1 wherein the implant further comprises a series of predetermined fracture lines such that after delivery into the sinus, the implant fractures into a plurality of segments.

38. The biodegradable implant of claim 1 wherein the sinus is a maxillary sinus, a frontal sinus, an ethmoid sinus, or a sphenoidal sinus.

39. The biodegradable implant of claim 1 wherein the sinus is the maxillary sinus.

40. A biodegradable implant for reducing inflammation from a sinus procedure comprising a sustained release therapeutic agent dispersed within a biodegradable matrix, wherein the biodegradable implant has at least one characteristic that substantially prevents clearance of the implant from a sinus during a treatment period after delivery of the implant into the sinus.

41. The biodegradable implant of claim 40 wherein the sinus procedure is a sinus drainage procedure.

42. The biodegradable implant of claim 40 wherein the sinus procedure enlarges a narrowed sinus ostium.

43. The biodegradable implant of claim 40 wherein the sinus procedure is antral puncture and washout.

44. The biodegradable implant of claim 40 wherein the sinus procedure is intranasal antrostomy.

45. The biodegradable implant of claim 40 wherein the biodegradable matrix is a biodegradable polymer matrix.

46. The biodegradable implant of claim 40 wherein the sustained release therapeutic agent is mometasone furoate.

47. A system for treating sinusitis comprising:

a) an implant delivery device, the implant delivery device comprising a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in said distal portion; and a pusher within the lumen; and

b) one or more biodegradable implants in the lumen of the implant delivery device, the one or more biodegradable implants comprising a sustained release therapeutic agent dispersed within a biodegradable matrix and having at least one characteristic that substantially prevents clearance of the one or more implants from a sinus during a treatment period after delivery of the one or more implants into the sinus,

wherein the one or more implants are delivered into the sinus by distally advancing the pusher to slidably engage the one or more implants and move the one or more implants through the opening in the distal portion of the conduit.

48. The system of claim 47 wherein the biodegradable matrix is a biodegradable polymer matrix.

49. The system of claim 47 wherein the distal portion of the conduit is angulated.

50. The system of claim 47 wherein the conduit is preloaded with a single implant.

51. The system of claim 47 wherein the conduit is preloaded with a plurality of implants.

52. The system of claim 47 further comprising a tool for visualizing the sinus ostium or sinus wall.

53. The system of claim 52 wherein the tool is an endoscope.

54. The system of claim 52 wherein the tool is a computed tomography scanner.

55. The system of claim 47 wherein the conduit is a needle.

56. The system of claim 47 wherein the conduit is a catheter.

57. The system of claim 47 wherein the conduit is malleable.

58. A method for delivering a biodegradable implant into a sinus comprising:

a) loading one or more biodegradable implants into a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in the distal portion;

b) accessing a sinus with the conduit;

c) deploying the one or more biodegradable implants through the opening in the distal portion of the conduit into the sinus,

wherein the one or more biodegradable implants comprise a therapeutic amount of an active agent for the treatment of sinusitis.

59. The method of claim 58 wherein the step of accessing comprises placing the conduit through a sinus ostium.

60. The method of claim 58 wherein the step of accessing comprises placing the conduit through a sinus wall.

61. The method of claim 58 wherein the step of deploying comprises slidably engaging the one or more biodegradable implants with a pusher and advancing the pusher within the conduit lumen.

62. The method of claim 58 wherein the step of deploying comprises contacting the one or more biodegradable implants with a pressurized gas.

63. The method of claim 58 wherein the distal portion of the conduit is angulated.

64. The method of claim 58 wherein the conduit is sharp-tipped.

65. The method of claim 58 wherein the opening is located in the side wall of the conduit.

66. The method of claim 58 wherein the opening is located at the tip of the conduit.

67. The method of claim 58 wherein the biodegradable implant is a biodegradable polymeric implant.

68. A method for delivering a biodegradable implant into a sinus comprising:

a) loading one or more biodegradable implants into a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in the distal portion;

b) accessing a sinus with the conduit;

c) deploying the one or more biodegradable implants through the opening in the distal portion of the conduit into the sinus,

wherein the one or more biodegradable implants comprise a therapeutic amount of an active agent for the reduction of inflammation from a sinus procedure.

69. The method of claim 68 wherein the step of accessing comprises placing the conduit through a sinus ostium.

70. The method of claim 68 wherein the step of accessing comprises placing the conduit through a sinus wall.

71. The method of claim 68 wherein the biodegradable implant is a biodegradable polymeric implant.

72. The implant of claim 68 wherein the active agent comprises mometasone furoate.